

AUG -1 2007

Research & Development 182 Susquehanna Ave Exeter, PA 18643 570-655-5574 FAX 655-2990 www.pridemobility.com

Device Description:

The Victory Four Wheel Scooter is a mid-size battery-operated scooter having a programmable 70-amp Digital Controller. Features include a removable molded plastic seat, a foldable tiller, and an off board charger. Additional safety features include electronic regenerative and electromechanical disc brakes, and rear anti-tip wheels. The Victory Four Wheel Scooter is designed for, but not limited to Pride Mobility Products Corp. providers / retailers and their consumers.

The Victory Four Wheel Scooter is designed with ultimate safety, stability, performance, and portability in mind. The main feature of the Scooter is a narrow wheelbase (22"), which allows better maneuverability from a mid-sized product.

Intended Use:

The intended use of the Pride Mobility Products Corp. Victory Four Wheel Scooter is to provide mobility to persons having limited walking capabilities.

Non-Clinical Testing:

Compliance to applicable Testing Standards is as follows:

ANSI/RESNA WC Vol. 1-1998 Requirements and Test Methods for Wheelchairs (Including Scooters)

ANSI/RESNA WC Vol. 2-1998 Additional Requirements for Wheelchairs (Including Scooters) with Electrical Systems

ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.

IEC 60335-2-29 Safety of Electrical Appliances (Part 2 Battery Chargers) IEC 601-1-1 Medical Electrical Equipment, General Requirements for Safety CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:

N/A

Conclusions:

The Victory Four Wheel Scooter has the same intended use and similar technological characteristics as the Legend SC340 (K930952), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Victory Four Wheel Scooter is substantially equivalent to the predicate device, has passed all testing requirements, and is considered to be safe for user operation.

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Exhibit 1

510(k) Summary Pride Mobility Products Corporation Victory Four Wheel Scooter

Submitter's Name & Address:

Pride Mobility Products Corporation 182 Susquehanna Avenue Exeter, Pa. 18643

Phone: (570) 655-5574 Facsimile: (570) 655-2990

Contact Person:

Thomas Schappert Official Correspondent

Date Prepared:

06-29-07

Name of Device and Proprietary Name:

Victory Four Wheel Scooter / Pride Mobility Products Corporation

Common or Usual Name:

Four-Wheel Power Scooter

Classification Name:

Physical Medicine / Motorized Three - Wheeled Vehicle

Product Code:

INI

Comparison to Predicate Devices:

The Victory Four Wheel Scooter is substantially equivalent to the Pride Mobility Legend SC340 (K930952) when comparing components, performance, maneuverability, stability, and structure. The performance characteristics and the position of the electronics and drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance. The differences between The Legend SC340 (K930952) and the Victory Four Wheel Scooter are in the wheelbase, front and rear frame construction, and the Control Mechanisms.

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Pride Mobility Products Corporation % Mr. Thomas Schappert 182 Susquehanna Avenue Exeter, PA 18643

AUG - 1 2007

Re: K071949

Trade/Device Name: Victory Four Wheel Scooter

Regulation Number: 21 CFR 890.3800

Regulation Name: Motorized three-wheeled vehicle

Regulatory Class: Class II

Product Code: INI Dated: August 7, 2007 Received: August 12, 2007

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

Page 2 – Mr. Thomas Schappert

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Director
Division of General, Restorative and Neurological Devices
Office of Device

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K	
Device Name: Victory Four Wheel Sco	oter
Indications for Use:	
The intended use of the Pride Mobility Products Corporation Victory Four Wheel Scooter, is to provide mobility to persons having limited walking capabilities.	
Prescription Use X AND / OR (Part 21 CFR 801 Subpart D)	Over-The-Counter Use X (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW 1 PAGE IF NEEDED)	THIS LINE-CONTINUE ON ANOTHER
Concurrence of CDRH, Office	e of New Co Estatuation (ODE) (Division Sign-Off)
	Division of General, Restorative,
	and Neurological Devices Page 1 of 1
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